REMARKS

Upon entry of the instant amendment, claims 105, 108, 109, 112-115 and 118 will be amended. Claims 91-139 will remain pending.

Claim 105 has been amended to recite a method for preparing a wound-healing promoting material which comprises extracorporeally contacting at least living leukocytes with a sheet-shaped porous body to trap the at least living leukocytes on surfaces of pores of the porous body. This is in accordance with the disclosure throughout Applicants' originally filed application including, for example, page 25 of Applicants' specification, second paragraph, wherein it is disclosed that "Also, use of a material having gas permeability and having no moisture permeability is particularly preferable since use of such material facilitates oxygen delivery to blood cells and maintains cell activity for a longer period of time."

Amendments to the dependent claims are in conformance with the amendments to independent claim 105.

Accordingly, no new matter should be considered to be included in the amendment herein.

Reconsideration and allowance of the application are respectfully requested.

Response To Maintaining of Restriction Requirement

The Office Action has maintained the restriction requirement with claims 105-120 and 137-139 being under prosecution, and claims 91-104 and 121-136 standing withdrawn from consideration.

Applicants request rejoinder of the non-elected subject matter following allowance of the elected claims.

Response To Rejections Under 35 U.S.C. 102(b) and 103(a)

The following art based rejections are set forth in the Office Action:

(a) Claims 105 and 120 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,651,966 to Read et al. (hereinafter "Read") with support by Wakelyn et al. (Handbook of Fiber Chemistry, 1998 - hereinafter "Wakelyn").

(b) Claims 105-107, 115 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Read, and further in light of support by Seagull et al. (J. Cotton Science).

(c) Claims 105-115, 118-120 and 137-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Read, and further in view of U.S. Patent No. 5,407,581 to Onodera et al. (hereinafter "Onodera") in light of support of Jan et al. (J. General Physiology, 1973 – hereinafter "Jan").

(d) Claims 105-107, 115-117 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Read, and further in view of US 2003/007957 A1 to Britton et al. (hereinafter "Britton").

In response to the rejections of record, Applicants point out that independent claim 105, as amended, is directed to a method for preparing a wound-healing promoting material which comprises extracorporeally contacting at least living leukocytes with a sheet-shaped porous body to trap the at least living leukocytes on surfaces of pores of the porous body. Thus, according to Applicants' recited subject matter, a sheet-shaped porous body wherein at least living leucocytes are trapped is prepared to obtain a wound-healing promoted material. According to the claimed

subject matter, living leukocytes are physically trapped and retained at a porous region, and therefore the activity of living cells is maintained. In contrast, Read uses fixed-dried platelets as compared to living leukocytes as recited in Applicants' independent claim 105 and claims dependent therefrom.

The differences between Read and Applicants' claimed subject matter is readily evident from the full disclosure of Read. For example, in the Summary of the Invention section of Read, it is disclosed that there are three aspect the Read invention, as follows:

> A first aspect of the present invention is fixed-dried human blood platelets which, upon reconstitution: (a) adhere to thrombogenic surfaces; (b) do not adhere to non-thrombogenic surfaces; (c) undergo shape change (spreading) upon adhering to a thrombogenic surface; (d) adhere to one another to form a hemostatic plug upon adhering to a thrombogenic surface; and (e) release their granular contents, such as after stimulation and/or spreading (e.g., after receiving a physiological stimulation which would ordinarily cause a metabolically active, live or fresh platelet to release its granular contents, such as contacting wounded tissue).
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> A second aspect of the present invention is a pharmaceutical formulation comprised of a fixed-dried blood platelets preparation. The fixed-dried blood platelet preparation comprises fixed-dried human blood platelets having the characteristics set forth above.
>
> A third aspect of the present invention is a method of fixing blood platelets to produce fixed-dried blood platelets having the characteristics set forth above, and the platelets so produced. The method comprises contacting the platelets to a fixative such as formaldehyde, paraformaldehyde, glutaraldehyde, or permanganate (e.g., by mixing the platelets with a solution thereof) for a time sufficient to fix or stabilize the platelets but insufficient to cause loss of the characteristics enumerated above. The platelets are then dried to yield fixed-dried blood platelets having the characteristics set forth above.

Thus, in Read, fixed-dried platelets having no cell activity are used in the preparation method. In contrast, according to the presently claimed subject matter, by preparing a wound-healing promoting material which comprises extracorporeally contacting at least living leukocytes with a sheet-shaped porous body to trap the at least living leukocytes on surfaces of pores of the porous body, there is able to be obtained a wound-healing promoting material

wherein living leukocytes are physically trap in the porous body. Therefore, cell activity is not lost according to Applicants' method of preparing a would-healing promoting material as is the case with Read's fixed-dried platelets. The living leucocytes on Applicants' prepared wound-healing promoting material can be directly contacted with a wound region, and thus wound-healing function in the living body can. be promoted. The claimed subject matter is clearly different from Read's method of preparation, and there is no teaching or suggestion in Read to arrive at Applicants' claimed method of preparing a wound-healing promoting material.

Wakelyn is used in the rejections solely to try and establish that the woven or nonwoven cotton inherently has pores. Whether or not this is the situation, Wakelyn does not overcome any of the above-noted deficiencies of Read.

Further, the Office Action alleges that certain dependent claims are obvious based upon Read in view of Seagull, Onodera in light of support from Jan, or Britton. In these rejections, only Onodera is used in the rejections for its disclosure of leukocytes. In this regard, Seagull is only used in an attempt to try and establish obviousness of Applicants' recited fiber diameters; Jan is used in an attempt to establish , "This charge injection would inherently exclude erythrocytes since their surface is negatively changed and thus repelled by a negative surface charge as supported by Jan et al. (introduction, 1st paragraph)"; and Britton is only used in an attempt to try and establish use of fibroblasts or fibrins. Applicants submit that whether or not it would be been obvious to combine Seagull and Britton with Read or that Jan establishes inherency as asserted in the rejection, Applicants' claimed subject matter would not be at hand. Any combination of the disclosures would not have arrived at Applicants' subject matter as recited in independent claim 105 and further patentably defined in the dependent claims.

Moreover, Onodera discloses trapping of blood components, such as platelets and leukocytes. However, Onodera discloses removing components from blood, and not for arriving at the preparation of a wound-healing promoting material.

For example, attention is directed to the Summary of the Invention section of Onodera, wherein it is disclosed that:

> The present inventors have made extensive and intensive studies with a view toward developing a filter medium which is capable of suppressing an increase in the bradykinin concentration of a blood material when the blood material is contacted with the filter medium for treatment of the blood material, so that even when the treated blood material is returned to a recipient, the recipient will not suffer from anaphylactic reactions caused by an increased bradykinin concentration. As a result of these studies, it has unexpectedly been found that the conventional filter media, which have a large quantity of negative charge introduced for improving the wettability thereof with blood, are likely to cause an increase in the bradykinin concentration of the blood material when they are used for treating the blood material, frequently leading to the occurrence of anaphylactic symptoms, that when the concentration of bradykinin in plasma of blood is increased to a level of 4,000 pg/ml or more of the plasma, serious anaphylactic symptoms are likely to occur, and that when a filter medium having a surface electric charge of not smaller than -30 μeq/g of the filter medium is used for treating blood, an increase in bradykinin content of the blood upon being contacted with the filter medium can be suppressed to maintain the bradykinin concentration in the blood at a level well below 4,000 pg/ml of the plasma of the blood, so that occurrence of serious anaphylactic symptoms is successfully prevented. The present invention has been completed, based on such novel findings.
>
> Accordingly, it is an object of the present invention to provide a filter medium for treating a blood material, which can satisfactorily suppress an increase in bradykinin concentration of a blood material upon being contacted with the blood material.
>
> It is another object of the present invention to provide a filter medium free of the bradykinin problem, for use in removing leukocytes from a leukocyte-containing suspension, including whole blood.
>
> It is still another object of the present invention to provide a filter membrane free of the bradykinin problem, for use in separating an undesired substance from whole blood or plasma.
>
> It is a further object of the present invention to provide an adsorptive composite type filter medium free of the bradykinin problem, for use in removing an undesired substance from whole blood or plasma.

> It is still a further object of the present invention to provide an apparatus for treating a blood material having packed therein a filter medium for removing leukocytes from a leukocyte-containing suspension or having packed therein an adsorptive composite type filter medium for removing an undesired substance from whole blood or plasma.

Thus, Read discloses that dried-fixed platelets are used according to his invention, and Onodera discloses treatment of blood for removing components so that the blood can be returned to the body. Certainly, one having ordinary skill in the art would not have been motivated to combine the diverse disclosures of Read and Onodera. Moreover, Read specifically discloses the use of fixed-dried platelets to form his surgical aid, and one having ordinary skill in the art would not have been motivated to combine the disclosure of Onodera to separate blood components with the forming of surgical aids disclosed by Read. The Examiner is reminded that there must be a reason why one having ordinary skill in the art would have combined the diverse disclosures of Read and Onodera. In the instant situation there is no reason outside Applicants' disclosure to arrive at Applicants' claimed subject matter.

Moreover, Applicants note that that the present invention provides a number of advantages. These advantages cannot be achieved by using fixed-dried platelets as disclosed by Read, and are not taught or suggested by any combination of the prior art used in the rejections of record. Thus, the present invention has at least the advantageous effects, as follows:

(1) Growth factor which is produced by leucocytes contributes to the promotion of cell growth ability in tissue and the regeneration of the tissue.

(2) Growth factor which is produced by a living cell acts on this living cell per se (self-secretion), and more strong action is obtained. Further, growth factor which is produced from the adjacent cells and is diffused acts on (paracrine system), and thus effects are enhanced intercellularly.

(3) Leucocytes from peripheral blood promote neoangiogenesis and produce new blood flow. Thus, wound-healing is promoted.

(4) The monocyte fraction in peripheral blood is differentiated into cells such as epithelial cell, vascular endothelial cell, liver cell, and nerve cell, and is expected to show wound-healing effect.

Still further, Applicants point out that claim 120 is directed to a wound-healing promoting material which is obtained by the method for preparing a wound-healing promoting material according to claim 105. For at least the reasons set forth above, claims 120 is allowable over any combination of the documents used in the rejections of record.

CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the restriction requirement and rejections of record, and allow all the pending claims.

Allowance of the application is requested, with an early mailing of the Notices of Allowance and Allowability.

If the Examiner has any questions or wishes to further discuss this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,
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